REMARKS

Claims 1-10 and 21-25 are pending in the application.

Claims 11-20 have been withdrawn from consideration by a restriction requirement by the Examiner under 37 CFR § 1.142(b). Applicant affirms the election of Group I, claims 1-10 and 21-24.

Claims 1, 5-7 and 21-24 were rejected under 35 U.S.C. § 102 as being anticipated by Stone et al.

Claims 21-22 were rejected under 35 U.S.C. § 102 as being anticipated by McDowell.

Claims 21-22 were rejected under 35 U.S.C. § 102 as being anticipated by the Dow Corning Wright Silastic Trapezial Implant H.P. Brochure ("Dow Corning") alone.

Claims 2-3 were rejected under 35 U.S.C. § 103 as being unpatentable over Stone et al. in view of Delcommune et al.

Claims 8-10 have been indicated as allowed by the Examiner over the prior art of record.

Applicant appreciates the indication that claim 4 has been indicated as allowable once formal changes have been made.

Formal Matters

Claim 6 was rejected under 35 U.S.C. § 112, second paragraph for being indefinite. Claim 6 has been amended to depend from claim 5 such that "said complementary surface shapes" now has proper antecedent basis. Claim 6 is now allowable.

Applicant believes that claims 21, 22 and 24 comply with 35 U.S.C. § 112, second paragraph. For example, claim 21 has been amended to recite "at least one surface being one or more" as suggested by the Examiner.

Claim 22 does not involve a "permanent, non-bioresorbable implant" to maintain the space in the joint as

stated by the Office Action. Claim 22 recites a first step of using a biocompatible insert to provide a space against which the fibrocartilage can develop. The relative movement between the first and second surfaces would still move along the cancellous bone surface formed by the fibrocartilage with the biocompatible insert and second surface moving as a unit in relation to the first surface cancellous bone surface.

Claim 24 has been amended to recite "placing a bioresorbable implant" between the surfaces and "waiting for the body to gradually resorb the implant" so that there is sufficient structural connection during the permitting step. Thus, claims 21, 22 and 24 are allowable.

Applicant notes that dependent claim 4 has been indicated as allowable once formal changes have been made to include all of the limitations of the base claim and any intervening claims. Dependent claim 4 has been rewritten as independent claim 25 and incorporates the limitations of claims 1, 2 and 4 and is allowable.

The Invention

Applicant's invention is directed toward a method for treating a joint using a bioresorbable implant. The bioresorbable implant 23 is constructed, for example, from a lactic acid polymer with a smooth, non-porous head 24 and a stem 26 (Figure 2). The lactic acid polymer and copolymer permits the body to hydrolyze or resorb the implant leaving no trace of the implant.

In the disclosed embodiment and method, the head 14 of the humerus is removed to expose a flat, raw or cancellous bone surface 20. A cavity 21 is power burred into the medullary canal where stem 26 is implanted. The opposite side of the joint is also resected to form a second cancellous bone surface. The

wound is then closed and used under normal conditions. The bioresorbable implant 23 maintains a space between the two cancellous bone surfaces and is permitted to be resorbed by the body through a hydrolysis process. Friction against the implant causes blood clot to form on the resected cancellous bone surface which later forms into a fibroblast. The fibroblast undergoes fibroplasia eventually progressing into fibrocartilage.

The Cited Art

The patent to Stone discloses a prosthetic articular cartilage device 10 with a porous volume matrix 12 of biocompatible and at least partially resorbable fibers. Some of the fibers may be constructed of collagen with a matrix of polysaccharides. Porous volume matrix 12 is constructed in a cylindrical disk shape with an internal scaffold structure to allow the ingrowth of articular chondrocytes. A conical, rigid base component 20 extends downward from the underside of matrix 12 to impact and anchor the articular cartilage device 10 into the bone 450. Matrix 12 remains flush with the surface of the pre-existing articular cartilage.

McDowell teaches using a plurality of spacers 34 to regenerate joint articular cartilage. The spacers 34 are formed from a polypropylene material with a head 36 and a shaft 38. The spacers 34 are inserted into one side of the joint to provide a space between the surfaces of the joint. The spaces formed between each spacer 34 allow for regeneration and growth of the remaining articular cartilage. After the articular cartilage has grown, the spacers 34 are then removed.

The Dow Corning brochure shows the use of a silicone implant as an interpositional spacer between the trapezium and the first metacarpal joint of the thumb. The implant consists of a head and a short, wide stem which is placed in the bone. The

implant is intended as a long term replacement for the joint structure.

The patent to Delcommune discloses the use of a lactic acid polymer as a biodegradable prosthesis for use in bone surgery.

The Cited Art Distinguished

Claims 1, 5-7 and 21-24 were rejected as being anticipated by Stone et al. However, the present invention differs from Stone in that the prosthetic articular cartilage device 10 in Stone has no smooth, non-porous surface (claim 1) and is not placed in the medullary canal (claim 7). The smooth, non-porous surface itself allows for the effect of friction to stimulate fibroplasia in the fibroblasts needed to form the fibrocartilage. Even if it were assumed that Stone did have a smooth surface (which it does not), the Stone method would then be rendered inoperable. The porous matrix 12 in Stone is designed to allow migration of the articular chondrocytes into the implant scaffold of implant 10 to begin regeneration in a cartilage-like structure. In a smooth, non-porous implant (Figure 2), such as the present invention, the articular chondrocytes would not be able to infiltrate any open spaces or scaffold and would not be able to regenerate into cartilage. The constant friction of the smooth, non-porous bioresorbable implant in the joint surface would also preclude any growth of articular cartilage by destroying any existing cartilage. In Applicant's invention, the smooth, non-porous surface acts to stimulate fibroblast development. The resulting surface of the inert, bioresorbable implant produces mechanical stimulation on the cancellous bone surface. Fibrocartilage then begins to form on the resected surface. The fibrocartilage develops on the outside of the implant as it is resorbed and not within the matrix structure as in Stone.

Moreover, there would be no motivation to use the Stone device in Applicant's method. The porous matrix 12 of Stone would allow for blood to penetrate and diffuse through the implant 10. No fibroblast clot would readily form in the scaffold structure of Stone and fibroplasia could not begin as required by Applicant's method. The use of a smooth, non-porous surface facilitates the formation of the blood clot through friction with the implant surface. The resected surface rubs against the bioresorbable implant which forms a fibroblast and later progresses into fibrocartilage. Thus, the Stone matrix would provide no support for Applicant's invention.

Additionally, Stone does not suggest forming a cavity in the medullary canal as in Applicant's method. Stone discloses extending the conical, rigid base component 20 into the cancellous bone structure 450 (Figure 9). However, this is not the medullary canal or marrow as in the present invention. The implanting of the Stone base component 20 into the cancellous bone 450 would only provide a limited blood supply. The high concentration of blood vessels in the marrow allows for the close proximity of a developing fibroblast and the bioresorbable implant. There would be no motivation to place the base component 20 into the medullary canal since the base component is used to anchor and secure the implant device 10 into the bone and allows the matrix portion 12 to remain flush with the existing articular cartilage. In the present invention, the medullary canal provides for a high supply of blood to the joint area. A blood clot will readily form and progress into the fibrocartilage. Thus, Stone does not anticipate Applicant's invention.

Claims **21-22** were rejected as being anticipated by McDowell alone and the Dow Corning brochure alone. However, the implants in McDowell and Dow Corning do not provide for growth of fibrocartilage on the resected cancellous surface. McDowell does not disclose or suggest using the implant spacers 34 against a raw, resected cancellous bone surface. McDowell teaches the use

of spacers which are implanted to provide space between the two joint surfaces to allow the articular cartilage to regenerate. One joint surface is generally an artificial humeral head with the artificial surface contacting the head 36 of the spacer. The shaft 38 is only implanted into the bone to keep the spacer in place. No bone surface is exposed to allow the formation of new fibrocartilage as in Applicant's invention. The spacers 34 only function to prevent the constant joint friction from destroying the already damaged articular cartilage. The spacers may also be removed upon the regeneration of articular cartilage. No new cartilage is formed and at least a small portion of existing articular cartilage is needed for the McDowell invention to be operable, unlike the present invention. If a joint had no articular cartilage, then no further cartilage would be regenerated. In Applicant's method, the resection of the bone allows for a fibroblast to form in close proximity to the implant. The fibroblast then undergoes fibroplasia which then forms fibrocartilage. Thus, McDowell does not anticipate Applicant's invention.

The Dow Corning brochure is cited for disclosing the use of an implant in a joint surface. However, the Dow Corning method does not allow for the formation of fibrocartilage in a joint if used and functioning properly. The implant is placed in a resected cancellous bone surface to maintain a spacing between the cancellous bone and second joint surface. This space is not the space between an implant and the cancellous bone surface as in the present embodiment. The Dow Corning implant is constructed of silicone which is intended as a permanent replacement for the cartilage in the joint not as a bioresorbable spacer to allow for fibrocartilage formation. The "short, wide stem" of the implant is essential to maintaining the position of the implant in the bone and keep the implant in place against the opposite joint surface. If the Dow Corning silicone implant does not degrade or shift, then no space would be available along the cancellous bone surface to allow for fibrocartilage growth in the

joint as in the present method. Thus the Dow Corning invention does not anticipate applicant's invention.

The office action cites Stone et al. in view of Delcommune for disclosing the use of a lactic acid polymer in joint implant. However, nothing in Stone would suggest using the Delcommune lactic acid polymer in a joint implant. In the present invention, the lactic acid polymer (claims **2** and **3**) is designed to be resorbed by the body during fibrocartilage formation on the cancellous bone surface. In fact, Stone teaches away from using a polymer with no matrix in the implant structure. The use of collagen and polysaccharides provides the necessary matrix 12 in Stone. The open matrix forms the scaffold for articular chondrocyte migration. There would be no motivation to use the lactic acid polymer as the chondrocytes would have no structure to infiltrate and develop into cartilage. In the present invention, no matrix structure is used or needed in the lactic acid polymer of the implant. The lactic acid polymer provides for the friction against the exposed cancellous bone and stimulation of fibrocartilage growth. Thus, Applicant's invention would not have been obvious over Stone in view of Delcommune.

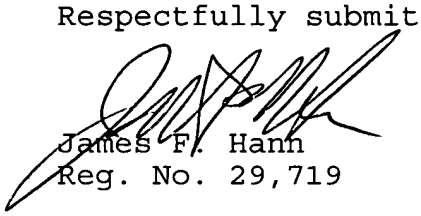
In summary, it is seen that applicant's invention would not have been obvious in view of the cited art because the prior art does not provide for a non-porous bioresorbable implant which is placed into the resected cancellous bone surface and medullary canal of at least one surface of a joint (claims **1, 7**). The resulting method allows for the movement of the resected surface against the implant stimulating formation of fibrocartilage. The implant is completely resorbed after a period of time leaving only fibrocartilage without a trace of the implant.

CONCLUSION

In view of the foregoing, Applicant believes all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at (415) 326-2400.

Respectfully submitted,



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A P P E N D I X

1. (Amended) A method for treating a joint having first and second mating joint surfaces comprising the following steps:
removing at least a portion of the first joint surface so to expose a cancellous bone surface;
selecting a non-porous bioresorbable implant;
placing [a] the bioresorbable implant between and in contact with the first and second joint surfaces so the implant initially keeps said exposed cancellous bone surface spaced apart from the second joint surface;
using the joint; and
whereby the cancellous bone surface initially forms fibroblast which progresses into fibrocartilage as the implant is resorbed so the fibrocartilage effectively replaces the implant during such resorption.

2. The method of claim 1 further comprising the step of selecting the bioresorbable implant made of a polymer of lactic acid.

3. The method of claim 2 wherein the selecting step is carried out by selecting a lactic acid copolymer.

4. The method of claim 1 further comprising the steps of:
estimating the period of time it will take for the fibroblast to progress into fibrocartilage; and
selecting the bioresorbable implant of a size, shape and material according to said period of time.

5. The method of claim 1 further comprising the step of ensuring the exposed cancellous bone surface and the step of ensuring the exposed cancellous bone surface and the surface of the bioresorbable implant placed against said bone surface have complementary surface shapes.

6. (Amended) The method of claim [3] 5 wherein the ensuring step includes the step of selecting curved surface shapes as said complementary surface shapes.

7. (Amended) The method of claim 1 further comprising the steps of:
forming a cavity into the medullary canal of the exposed cancellous bone surface; and
selecting a non-porous bioresorbable implant having a joint portion configured to fit between the first and second joint surfaces and a stem portion configured to fit within said cavity.

8. A method for treating a substantially non-weight bearing arthritic joint having first and second mating joint surfaces comprising the following steps:
removing at least a portion of the first and second joint surfaces so to expose first and second cancellous bone surfaces;
selecting a bioresorbable implant having first and second implant surfaces corresponding to the first and second cancellous bone surfaces;
placing the first and second implant surfaces of the bioresorbable implant between and against the first and second exposed bone surfaces; and
using the joint;
wherein the cancellous bone surfaces initially form fibroblast which progress into fibrocartilage at each said bone surface as the implant is resorbed, thereby effectively replacing the implant during such resorption.

9. The method of claim 8 wherein the selecting step is carried out by selecting said bioresorbable implant having a generally semi-spherical joint surface as the first implant surface.

10. The method of claim 8 further comprising the steps of:

estimating the period of time it will take for the fibroblast to progress into fibrocartilage; and

selecting the bioresorbable implant of a size and material according to said period of time.

21. (Amended) A method for treating at least one degenerated surface on a cancellous bone, the at least one surface being one or more of first and second relatively movable surfaces defining a body joint, the method comprising the steps of resecting the bone to [form] expose a cancellous bone surface, maintaining a spacing between the cancellous surface and another one of the relatively movable surfaces of the body joint, permitting growth of fibroblast on the cancellous surface and conversion of the fibroblast into fibrocartilage, and maintaining at least a portion of the spacing during the permitting step and until the fibrocartilage forms a layer of fibrocartilage on the cancellous surface and defines at least one of the relatively moveable surfaces of the bone joint so that thereafter relative movements between the first and second surfaces take place along the at least one surface formed by the fibrocartilage.

22. The method of claim 21 wherein the first maintaining step is carried out by placing a biocompatible insert against said surfaces.

23. The method of claim 21 wherein the first maintaining step is carried out by placing a bioresorbable implant between said surfaces.

24. (Amended) A method for treating at least one degenerated surface on a cancellous bone, the surface being one of first and second relatively movable surfaces defining a body joint, the method comprising the steps of resecting the bone to form a cancellous bone surface, placing a[n] bioresorbable implant between the first and second surfaces to thereby space the surfaces apart, permitting growth of fibroblast on the cancellous surface and conversion of the fibroblast into fibrocartilage, maintaining a spacing between the surfaces during the permitting step and [gradually resorbing] waiting for the body to gradually resorb the implant during the permitting step so that, upon resorption of the implant, the fibrocartilage forms at least one of the movable surfaces.

25. (New) A method for treating a joint having first and second mating joint surfaces comprising the following steps:

removing a least a portion of the first joint surface so to expose a cancellous bone surface;

placing a bioresorbable implant between and in contact with the first and second joint surfaces so the implant initially keeps said exposed cancellous bone surface spaced apart form the second joint surface;

using the joint;

whereby the cancellous bone surface initially forms fibroblast which progresses into fibrocartilage as the implant is resorbed so the fibrocartilage effectively replaces the implant during such resorption;

estimating the period of time it will take for the fibroblast to progress into fibrocartilage; and

selecting the bioresorbable implant of a size, shape and material according to said period of time.